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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,122	08/10/2006	Barry Peter Liversidge	1926-00120	5703
26753	7590	03/01/2010	EXAMINER	
ANDRUS, SCEALES, STARKE & SAWALL, LLP			PATEL, SHEFALI DILIP	
100 EAST WISCONSIN AVENUE, SUITE 1100			ART UNIT	PAPER NUMBER
MILWAUKEE, WI 53202			3767	
MAIL DATE		DELIVERY MODE		
03/01/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,122	Applicant(s) LIVERSIDGE, BARRY PETER
	Examiner SHEFALI D. PATEL	Art Unit 3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11/16/2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 1-20 is/are allowed.
 6) Claim(s) 21-32 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No./Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No./Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Acknowledgments

1. In the reply, filed on November 16, 2009, Applicant amended claims 1, 20, 21, 31, and 32.
2. Currently, claims 1-32 are under examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 21-24, 26-28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rand et al (US 5,137,516), and further in view of Sempere (EP 0409180).

In regards to claims 21-24, 26-28, and 30, Rand et al teaches a handling device (Figures 17-24, second cap [132]) for use with a medical injector (syringe [16] with sleeve assembly [23]) having a cylindrical body (barrel [17]) provided with a boss at the forward end thereof supporting a forwardly-projecting needle (needle [19]) furnished with a substantially rigid protective sheath (septum [20]), which device [132] comprises:

- a. a carrier [132] having an outer cylindrical wall and co-axial therewith an inner tube (cylindrical protrusion [137]) which is a close sliding fit over said substantially rigid protective sheath [20] of the needle [19] (Figures 23-24)

Rand et al does not teach a cylindrical sleeve slidably mounted within the outer cylindrical wall of the carrier, a bushing slidably located within the cylindrical sleeve, and a spring means urging the bushing towards the rear end of the sleeve. Sempere teaches a handling device (Figures 1-3) comprising a carrier (cover [9]), a cylindrical sleeve (sliding body [2]) slidably mounted within the outer cylindrical wall of the carrier, a bushing (body [1]) slidably located within the cylindrical sleeve, and a spring means (spring [8]) urging the bushing towards the rear end of the sleeve (column 2, lines 49-54). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the handling device, of Rand et al, with a sleeve, bushing, and spring means, as taught by Sempere, as the sleeve, bushing, and spring means will provide a protection of the needle by enclosing the needle automatically in the sleeve and bushing after one use, thus ensuring that the used, contaminated needle is no longer usable for subsequent applications (column 1, lines 7-12). *From Applicant's specification (page 8, line 15), the spring means is performed by a helical compression spring [29].*

In regards to claim 31, Rand et al teaches a medical injector (Figures 17-24, syringe [16] with sleeve assembly [23]) having a cylindrical body (barrel [17]) provided with a boss at the forward end thereof for supporting a forwardly-projecting needle (needle [19]) furnished with a protective sheath (septum [20]). Together Rand et al and Sempere teach a combination of the medical injector and a handling device, as claimed in claim 1 (*see rejection of claim 21 above*).

5. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rand et al and Sempere, as applied to claim 24 above, and further in view of Jangula (US 2005/0171484).

In regards to claim 25, in a modified device of Rand et al and Sempere, Sempere does not teach that the rear end of the sleeve [2] has radially-inwardly directed nibs with which the bushing [1] is engageable. Jangula teaches a handling device (Figures 2-4) wherein the rear end of a sleeve (bushing [46]) has radially-inwardly directed nibs (inward extending stop surfaces [48]) with which a bushing (cap [30] with adapter [40]) is engageable (Figure 4). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the sleeve, of the modified device of Rand et al and Sempere, with radially-inwardly directed nibs, as taught by Jangula, as the radially-inwardly directed nibs of the sleeve will act as a stop means to control and limit the forward movement of the bushing within the sleeve (paragraphs [0027][0028]).

6. Claims 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rand et al and Sempere, as applied to claim 21 above, and further in view of Pizzino (US 4,702,737).

In regards to claim 29, in a modified device of Rand et al and Sempere, Rand et al does not teach that the boss at the forward end of the cylindrical body [17] is externally screw-threaded, for use with a needle having a hub with an internally-threaded socket co-operable with the threads of the boss. Pizzino teaches an injector (Figure 1, syringe [10]) having a boss (externally screw threaded tubular conduit [46]) with external screw threads that are co-operable with the internal screw threads of a hub (internally screw threaded hub [52]) of a needle [48]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the boss and needle hub, of the injector of the modified device of Rand et al and Sempere, with threads, as taught by Pizzino, as such will provide a means for the attachment of a

needle to an injector and will provide a means to prevent re-use of a needle as a new needle will be screwed onto the injector for every use of the injector (column 2, lines 63-68 to column 3, lines 1-8).

In regards to claim 32, with a modified device of Rand et al and Sempere, Rand et al teaches a method of using a handling device [132], as claimed in claim 21, with a medical injector [16][23] having a cylindrical body [17] provided with a boss at the forward end thereof for supporting a needle [19] and a substantially rigid needle sheath [20] surrounding and protecting the needle, comprising the steps of:

- a. pushing the carrier [132] on to the forward end of the injector [16][23], the sheath [20] is coupled to the inner tube [137] (column 11, lines 8-10)(column 12, lines 52-53)
- b. pulling the carrier [132] away from the cylindrical body [17] of the injector [16][23] with the sheath [20] retained within the inner tube [137] (column 12, lines 60-62)
- c. pushing the carrier [132] once more on to the forward end of the injector [16][23] to refit the sheath [20] on the needle [19] (column 13, lines 3-5)

Rand et al does not teach pushing a carrier with a sleeve, a bushing, and a spring onto the injector, and pulling the carrier away from the injector to retain the sleeve and the bushing on the injector. Sempere teaches pushing a sleeve [2], a bushing [1], and a spring [8] onto an injector [4] (column 2, lines 25-39). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the method, of the modified device of Rand et al and Sempere, by pushing a sleeve, a bushing, and a spring onto the injector, as taught by Sempere, as the sleeve, bushing, and spring will provide a protection of the needle by enclosing

the needle automatically in the sleeve and bushing after one use, thus ensuring that the used, contaminated needle is no longer usable for subsequent applications (column 1, lines 7-12). Further, Rand et al does not teach that the injector [16][23] has an externally threaded boss for supporting the internal threads of a needle hub of a needle. Pizzino teaches an injector (Figure 1, syringe [10]) having a boss (externally screw threaded tubular conduit [46]) with external screw threads that are co-operable with the internal screw threads of a hub (internally screw threaded hub [52]) of a needle [48]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the boss and needle hub, of the injector of the modified device of Rand et al and Sempere, with threads, as taught by Pizzino, as such will provide a means for the attachment of a needle to an injector and will provide a means to prevent re-use of a needle as a new needle will be screwed onto the injector for every use of the injector (column 2, lines 63-68 to column 3, lines 1-8).

Response to Arguments

7. Applicant's arguments, see pages 11-12, filed on November 16, 2009, with respect to claims 1-20, rejected under 35 USC 103(a) as being unpatentable over Rand, in view of Sempere and/or other references, have been fully considered and are persuasive. The rejection of claims 1-20 of July 14, 2009, has been withdrawn.

8. Applicant's arguments filed on November 16, 2009, have been fully considered but they are not persuasive:

In regards to claims 21-24, 28, 30, and 31, Applicant argues that Applicant's substantially rigid sheath can clearly be distinguished from the rubber septum [20] of Rand, since the septum

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[20] is permanently secured within the second cap [132] and is not the equivalent structure of the rigid sheath of Applicant (Reply, pages 15-16). However, claim 21 only requires the needle to be furnished with a protective sheath. Rand teaches a needle [19] that is furnished with a protective sheath [20]. Claim 21 does not preclude interpretation of a sheath [20] that is permanently secured within a carrier [132], as taught by Rand. Claim 21 does not require the sheath to originally be a component of the medical injector and not a component of the carrier.

In further regards to claims 21-24, 28, and 30, Applicant argues that the rubber septum [20] of Rand is not substantially rigid like the protective sheath of Applicant and that the septum of Rand must be resiliently flexible (Reply, page 15). However, even though rubber is primarily a flexible material, rubber still has some degree of rigidity and can be considered both flexible and rigid. Hence, the rubber septum [20] of Rand is a substantially rigid protective sheath, as required by claim 21.

Allowable Subject Matter

9. Claims 1-20 are allowed. The following is a statement of reasons for the indication of allowable subject matter:

In regards to claim 1, the prior art of record does not disclose or render obvious at the time the invention was made the combination as claimed, specifically including a plug mounted on the carrier of a medical injector handling device, wherein the plug slides between an inactive position where the plug is located substantially wholly within the carrier and an indicating position where the plug projects from the carrier, the plug having a wall disposed for engagement

by a forward end of a protective sheath of a needle to effect the sliding movement. Claims 2-20 are allowed by virtue of being dependent upon allowable independent claim 1.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
02/25/2010
/Kevin C. Sirmons/
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